

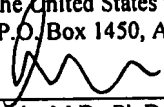
DOCKET NO.: C1039.70048US00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Arthur M. Krieg  
Serial No.: 10/644,052  
Confirmation No.: 4791  
Filed: August 19, 2003  
For: IMMUNOSTIMULATORY NUCLEIC ACIDS  
  
Examiner: Not yet assigned  
Art Unit: 1632

**CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)**

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 30th day of September, 2005.

  
Alan W. Steele, M.D., Ph.D., Reg. No. 45,128

**MAIL STOP AMENDMENT**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**TRANSMITTAL**

Sir:

Transmitted herewith are the following documents:

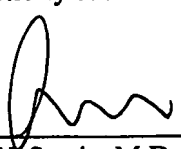
- ☒ Supplemental Statement Filed Pursuant to the Duty of Disclosure Under 37 CFR §§1.56, 1.97 and 1.98
- ☒ Copy of Letter from Andrew Chin
- ☒ Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 646-8000, Boston, Massachusetts.

No check is enclosed. If a fee is required, please charge to Deposit Account 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,

By:

  
Alan W. Steele, M.D., Ph.D., Reg. No. 45,128  
Wolf, Greenfield & Sacks, P.C.  
600 Atlantic Avenue  
Boston, Massachusetts 02210-2206  
Telephone: (617) 646-8000

Docket No.: C1039.70048US00  
Date: September 30, 2005  
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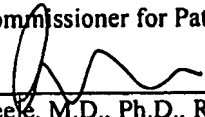
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**MAIL STOP AMENDMENT**

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P.O. Box 1450  
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**SUPPLEMENTAL STATEMENT FILED PURSUANT TO THE DUTY OF  
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98**

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Supplemental Information Disclosure Statement.

**PART I: Compliance with 37 C.F.R. §1.97**

This Supplemental Information Disclosure Statement has been filed before the mailing of a first Office action on the merits in the above-identified case. No fee or certification is required.

**PART II: Information Cited**

The Applicant would like to bring to the Examiner's attention the following other information (copy enclosed).

- Letter from Andrew Chin, dated May 12, 2005.

PART III: Remarks

It is respectfully requested that the Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims.

By submitting this Supplemental Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.


By submitting this Supplemental Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Supplemental Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

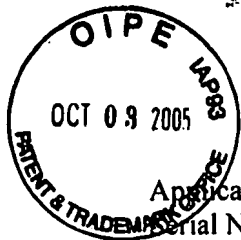
Notwithstanding any statements by the Applicant, the Examiner is urged to form his or her own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,

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Alan W. Steele, M.D., Ph.D., Reg. No. 45,128  
Wolf, Greenfield & Sacks, P.C.  
600 Atlantic Avenue  
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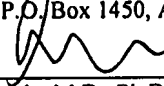
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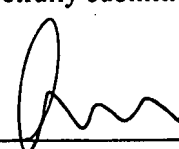
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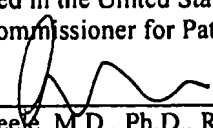
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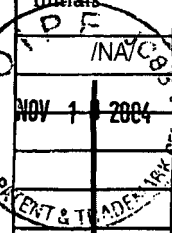



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Docket No.: C1039.70048US00  
Date: September 30, 2005  
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FORM PTO-1449/A and B (Modified)  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>		APPLICATION NO.: 10/644,052	ATTY. DOCKET NO.: C1037.70048US00
		FILING DATE: August 19, 2003	CONFIRMATION NO.: 4791
		APPLICANT: Krieg et al.	
		GROUP ART UNIT: 1632	EXAMINER: Not Yet Assigned
Sheet	1	of	2

**U.S. PATENT DOCUMENTS**

Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
	A42	5,968,909		Agrawal et al.	10-19-1999
	A43	6,727,230	B1	Hutcherson et al.	04-27-2004
	A44	6,821,957	B1	Davis et al.	11-23-2004
	A45	2003-0212026	A1	Krieg et al.	11-13-2003
	A46	2003-0224010	A1	Davis et al.	12-04-2003
	A47	2004-0030118	A1	Wagner et al.	02-12-2004
	A48	2004-0053880	A1	Krieg	03-18-2004
	A49	2004-0067905	A1	Krieg	04-08-2004
	A50	2004-0087534	A1	Krieg et al.	05-06-2004
	A51	2004-0087538	A1	Krieg et al.	05-06-2004
	A52	2004-0092472	A1	Krieg	05-13-2004
	A53	2004-0106568	A1	Krieg et al.	06-03-2004
	A54	2004-0131628	A1	Bratzler et al.	07-08-2004
	A55	2004-0132685	A1	Krieg et al.	07-08-2004
	A56	2004-0142469	A1	Krieg et al.	07-22-2004
	A57	2004-0143112	A1	Krieg et al.	07-22-2004
	A58	2004-0147468	A1	Krieg et al.	07-29-2004
	A59	2004-0152649	A1	Krieg	08-05-2004
	A60	2004-0152656	A1	Krieg et al.	08-05-2004
	A61	2004-0152657	A1	Krieg et al.	08-05-2004
	A62	2004-0162258	A1	Krieg et al.	08-19-2004
	A63	2004-0162262	A1	Krieg et al.	08-19-2004
	A64	2004-0167089	A1	Krieg et al.	08-26-2004
	A65	2004-0171150	A1	Krieg et al.	09-02-2004
	A66	2004-0171571	A1	Krieg et al.	09-02-2004
	A67	2004-0181045	A1	Krieg et al.	09-16-2004
	A68	2004-0198688	A1	Krieg et al.	10-07-2004

EXAMINER:  /Nina Archie/	DATE CONSIDERED:  06/06/2007
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#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

[NOTE - The Office hereby waives the requirement under 37 CFR 1.98 (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003 and for all international applications that have entered the national stage under 35 USC 371 after June 30, 2003. See 37 CFR 1.491(b). For all patent applications filed on or before June 30, 2003, copies of cited U.S. patents and patent application publications are still required unless an eIDS is filed. Copies of all other patent(s), publication(s), or other information listed must still be provided, even if it was previously submitted to, or cited by, the U.S. Patent Office in an earlier application, unless the earlier application is identified by the IDS and is relied upon for an earlier filing date under 35 U.S.C. §120, and the copy was provided in the earlier application.]

FORM PTO-1449/A and B (Modified)  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				APPLICATION NO.: 10/644,052		ATTY. DOCKET NO.: C1037.70048US00	
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				GROUP ART UNIT: 1632		EXAMINER: Not Yet Assigned	
Sheet	2	of	2				

#### FOREIGN PATENT DOCUMENTS

Examiner's Initials	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document (not necessary)	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/ Country	Number	Kind Code			
/NA/	B6	WO	2004/041183	A2	The Regents of the University of California	05-21-2004	

EXAMINER:	DATE CONSIDERED:
/Nina Archie/	06/06/2007

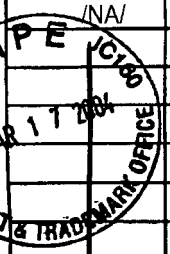
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FORM O-1449/A and B (Modified)		APPLICATION NO.: 10/644,052	ATTY. DOCKET NO.: C1037.70048US00
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		APPLICANT: Krieg et al.	
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Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
	#A1	4,469,863		Ts'o et al.	09-04-1984
	#A2	5,023,243		Tullis	06-11-1991
	#A3	5,663,153		Hutcherson et al.	09-02-1997
	#A4	5,723,335		Hutcherson et al.	03-03-1998
	#A5	6,194,388	B1	Krieg et al.	02-27-2001
	#A6	6,207,646	B1	Krieg et al.	03-27-2001
	#A7	6,207,819	B1	Manoharan et al.	03-27-2001
	#A8	6,214,806	B1	Krieg et al.	04-10-2001
	#A9	6,218,371	B1	Krieg et al.	04-17-2001
	#A10	6,239,116	B1	Krieg et al.	05-29-2001
	#A11	2001/0044416	A1	Davis et al.	11-22-2001
	#A12	6,339,068	B1	Davis et al.	01-15-2002
	#A13	2002/0064515	A1	Krieg et al.	05-30-2002
	#A14	6,406,705	B1	Davis et al.	06-18-2002
	#A15	2002/0091097	A1	Bratzler et al.	07-11-2002
	#A16	6,429,199	B1	Krieg et al.	08-06-2002
	#A17	2002/0156033	A1	Bratzler et al.	10-24-2002
	#A18	2002/0164341	A1	Davis et al.	11-07-2002
	#A19	2002/0165178	A1	Schetter et al.	11-07-2002
	#A20	2002/0198165	A1	Bratzler et al.	12-26-2002
	#A21	6,514,948	B1	Raz et al.	02-04-2003
	#A22	2003/0026782	A1	Krieg et al.	02-06-2003
	#A23	2003/0026801	A1	Weiner et al.	02-06-2003
	#A24	2003/0050261	A1	Krieg et al.	03-13-2003
	#A25	2003/0050263	A1	Krieg et al.	03-13-2003
	#A26	2003/0050268	A1	Krieg et al.	03-13-2003
	#A27	2003/0055014	A1	Bratzler	03-20-2003
	#A28	2003/0087848	A1	Bratzler et al.	05-08-2003
	#A29	6,562,798	B1	Schwartz et al.	05-13-2003
	#A30	2003/0091599	A1	Davis et al.	05-15-2003
	#A31	2003/0100527	A1	Krieg et al.	05-29-2003
	#A32	2003/0104523	A1	Lipford et al.	06-05-2003
	#A33	2003/0139364	A1	Krieg et al.	07-24-2003
	#A34	2003/0148316	A1	Lipford et al.	08-07-2003
	#A35	2003/0148976	A1	Krieg et al.	08-07-2003
	#A36	2003/0166001	A1	Lipford	09-04-2003
	#A37	2003/0181406	A1	Schetter et al.	09-25-2003
	#A38	2003/0191079	A1	Krieg et al.	10-09-2003
	#A39	6,653,292	B1	Krieg et al.	11-25-2003

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Sheet	2	of	3				

#A40	2003/0232074	A1	Lipford et al.	12-18-2003
#A41	2004/0009949	A1	Krieg	01-15-2004

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		Office/ Country	Number	Kind Code			
/NA/	B1	EP	0 092 574	B1	Molecular Biosystems, Inc.	04-29-1992	
↓	B2	WO	99/56755	A1		11-11-1999	
	B3	WO	00/06588	A1		02-10-2000	
	B4	WO	02/26757	A2	Hybridon, Inc.	04-04-2002	
	B5	WO	02/069369	A2		09-06-2002	

#### OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
/NA/	C1	BEAUCAGE SL et al., Deoxynucleoside phosphoramidites — a new class of key intermediates for deoxypolynucleotide synthesis. <i>Tetrahedron Lett.</i> 1981;22:1859-62.	
	C2	COHEN PA et al., CD4+ T-cells from mice immunized to syngeneic sarcomas recognize distinct, non-shared tumor antigens. <i>Cancer Res.</i> 1994 Feb 15;54(4):1055-8.	
	C3	FROEHLER BC et al., Synthesis of DNA via deoxynucleoside H-phosphonate intermediates. <i>Nucleic Acids Res.</i> 1986 Jul 11;14(13):5399-407.	
	C4	GAFFNEY BL et al., Large-scale oligonucleotide synthesis by the H-phosphonate method. <i>Tetrahedron Lett.</i> 1988;29:2619-22.	
	C5	GAREGG PJ et al., Nucleoside H-phosphonates. III. Chemical synthesis of oligodeoxyribonucleotides by the hydrogenphosphonate method. <i>Tetrahedron Lett.</i> 1986;27:4051-4.	
	C6	GAREGG PJ et al., Nucleoside H-phosphonates. IV. Automated solid phase synthesis of oligoribonucleotides by the hydrogenphosphonate approach. <i>Tetrahedron Lett.</i> 1986;27:4055-8.	
	C7	GHOSH MK et al., Phosphorothioate-phosphodiester oligonucleotide co-polymers: assessment for antisense application. <i>Anticancer Drug Des.</i> 1993 Feb;8(1):15-32.	
	C8	GOODCHILD J, Conjugates of oligonucleotides and modified oligonucleotides: a review of their synthesis and properties. <i>Bioconjug Chem.</i> 1990 May-Jun;1(3):165-87.	
	C9	HACKER H et al., CpG-DNA-specific activation of antigen-presenting cells requires stress kinase activity and is preceded by non-specific endocytosis and endosomal maturation. <i>EMBO J.</i> 1998 Nov 2;17(21):6230-40.	
	C10	HARTMANN G et al., CpG DNA: a potent signal for growth, activation, and maturation of human dendritic cells. <i>Proc Natl Acad Sci U S A.</i> 1999 Aug 3;96(16):9305-10.	
	C11	KRIEG AM et al., CpG motifs in bacterial DNA trigger direct B-cell activation. <i>Nature.</i> 1995 Apr 6;374(6522):546-9.	
	C12	KRIEG AM et al., Oligodeoxynucleotide modifications determine the magnitude of B cell stimulation by CpG motifs. <i>Antisense Nucleic Acid Drug Dev.</i> 1996 Summer;6(2):133-9.	
	C13	LIANG H et al., Activation of human B cells by phosphorothioate oligodeoxynucleotides. <i>J Clin Invest.</i> 1996 Sep 1;98(5):1119-29.	
	C14	LIPFORD GB et al., Bacterial DNA as immune cell activator. <i>Trends Microbiol.</i> 1998 Dec;6(12):496-500.	
	C15	MANNON RB et al., Stimulation of thymocyte proliferation by phosphorothioate DNA oligonucleotides. <i>Cell Immunol.</i> 2000 Apr 10;201(1):14-21.	
↓	C16	MESSINA JP et al., Stimulation of in vitro murine lymphocyte proliferation by bacterial DNA. <i>J Immunol.</i> 1991 Sep 15;147(6):1759-64.	

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		FILING DATE: August 19, 2003	CONFIRMATION NO.: unknown
		APPLICANT: Krieg et al.	
		GROUP ART UNIT: unknown	EXAMINER: unknown
Sheet	3	of	3

have it	C17	MUI B et al., Immune stimulation by a CpG-containing oligodeoxynucleotide is enhanced when encapsulated and delivered in lipid particles. <i>J Pharmacol Exp Ther.</i> 2001 Sep;298(3):1185-92.		
/NA/	C18	PEYMAN A et al., Minimally modified oligonucleotides - combination of end-capping and pyrimidine-protection. <i>Biol Chem Hoppe Seyler.</i> 1996 Jan;377(1):67-70.		
	C19	PISETSKY DS, The immunologic properties of DNA. <i>J Immunol.</i> 1996 Jan 15;156(2):421-3.		
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	C23	WAGNER RW et al., Potent and selective inhibition of gene expression by an antisense heptanucleotide. <i>Nat Biotechnol.</i> 1996 Jul;14(7):840-4.		
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	C26	ZHAO Q et al., Effect of different chemically modified oligodeoxynucleotides on immune stimulation. <i>Biochem Pharmacol.</i> 1996 Jan 26;51(2):173-82.		
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EXAMINER	/Nina Archie/	DATE CONSIDERED	06/06/2007
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#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

\*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. \_\_, filed \_\_, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

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